IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARGARET A. HERICKS	:	CIVIL ACTION
	:	
v.	:	No. 07-387
	:	
LINCARE INC., et al.	:	

MEMORANDUM

Juan R. Sánchez, J. **March 25, 2014**

Plaintiff Margaret Hericks on behalf of the United States of America, pursues claims for violations of the False Claims Act (FCA), 31 U.S.C. § 3729(a)(1), (2), and (3), by Defendants Lincare, Inc. and Lincare Holdings, Inc. (collectively Lincare).[1] Defendants have filed a motion to dismiss for failure to state a claim as required by Federal Rule of Civil Procedure 8(a) and failure to plead fraud with particularity as required by Rule 9(b).[2] For the reasons set forth below, the motion will be granted.

[1] The original Complaint in this action was filed under seal in January 2007 and remained under seal until July 2012, when the Government declined to intervene. After the Complaint was unsealed and served on Defendants, Hericks filed an Amended Complaint (First Amended Complaint or FAC), which Defendants moved to dismiss. The Court heard oral argument on the motion, denied Defendants' motion without prejudice, and allowed Hericks to file a Second Amended Complaint (SAC). Hericks filed the SAC on March 28, 2013, and Defendants moved to dismiss. As such, the Court's discussion will concern the allegations set forth in the SAC unless otherwise stated.

[2] Defendants also assert the Court does not have personal jurisdiction over Lincare Holdings, Inc. (Holdings) because Hericks failed to plead any facts with respect to Holdings and her allegations involve only Lincare, Inc., requiring dismissal of any claims against Holdings pursuant to Federal Rule of Civil Procedure 12(b)(2). Defendants, however, rely on case law concerning a federal court's jurisdiction in cases involving state law claims against a holding company as a named defendant when the complaint focuses on the actions of the subsidiary company. Hericks claims are based exclusively on federal law, and she alleges specific allegations against Holding, independent of its position as a holding company of Lincare, Inc. Nowhere in the in the SAC does she assert the Court should impute the jurisdictional contacts of Lincare, Inc. to Holdings.

BACKGROUND

Lincare, Inc. and Lincare Holdings, Inc. together constitute a national oxygen and durable medical equipment (DME) company headquartered in Florida.[3] Lincare provides home oxygen and related therapies to patients suffering from chronic obstructive pulmonary disease (COPD) and congestive heart failure (CHF) at the patients' private residences. The company serves over 700,000 customers in 48 states through approximately 1,100 operating centers. From May 2004 to May 2005, Hericks worked for Lincare as a manager of a Lincare center in Livonia, Michigan.

Hericks alleges that since 2002, Lincare has given kickbacks to doctors through its Care Check program, in violation of the FCA. Under the Care Check program, Lincare directs its

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Her allegations against Holdings include, for example, that "[t]he Care Check training was conducted by Mr. Mickey McKenzie, National Director of Marketing and Business Development for Lincare Holdings, Inc., a position he holds today." SAC ¶ 27; *see also id.* ¶¶ 29, 30, 36. In addition, according to the regional sale manager for Hericks's region, "the Care Check program was implemented and developed by Shawn Schabel, who is currently the President and, since at least 2011, has been Chief Operating Officer of Lincare Holdings, Inc." SAC ¶ 28. These statements allege Holdings was directly involved in the allegedly false claims submitted to the Government.

Furthermore, when a federal court exercises jurisdiction pursuant to a federal statute it is the United States and not the particular state in which the court is located that is exercising jurisdiction and, therefore, all that is necessary to satisfy due process is that the defendant have minimum contacts with the United States. *See e.g.*, *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 365 (3d Cir. 2002) (finding the defendant company "purposely availed itself of the American securities market and thereby evidenced the requisite minimum contacts with the United States to support the exercise of personal jurisdiction by a federal court"); *United States v. Metzinger*, No. 94-7520, 1996 WL 412811, at *2 (E.D. Pa. July 18, 1996) (holding, in a case involving allegations of False Claims Act violations, "as defendants reside within the territorial boundaries of the United States, the minimum contacts with the United States, which are required to justify this Court's exercise of power over them, are present"). Hericks brings her claims pursuant to the FCA, which confers nationwide jurisdiction. *See Metzinger*, 1996 WL 412811, at *2 n.3. Holdings resides within the territorial boundaries of the United States, and thus, has sufficient minimum contacts with the United States that the Court's exercise of personal jurisdiction does not offend traditional notions of fair play and substantial justice. *See e.g.*, *id.* at *2; *United States v. Torkelsen*, No. 06-05674, 2007 WL 4245736, at *3 (E.D. Pa. Dec. 3, 2007). Accordingly, the Court has jurisdiction over Holdings.

[3] In August 2012, Lincare became a wholly owned subsidiary of The Linde Group.

employees to induce physicians and patients to generate referrals for the provision of medical equipment and services by Lincare, for which Lincare then seeks reimbursement under Medicare and other federal health insurance programs.

Hericks began working for Lincare in May 2004, and a month later she attended marketing training at Lincare's Columbus, Ohio center. While there, Lincare employees showed Hericks the list of Medicare patients Dr. Emmart Hoy had referred to Lincare as a result of the Care Check program. In August 2004, Hericks attended center manager training in Indianapolis, Indiana. The trainers—including David Morrison, Lincare's Regional Sales Manager for Hericks's region—used Lincare's Casper, Wyoming center as a teaching example and gave Hericks and the other trainees reports from that center. These reports showed that Lincare obtained many new Medicare oxygen patients through the Care Check program and listed claims submitted to Medicare by Lincare for medical equipment as a result of the program. In the SAC, Hericks provides three examples of Medicare claims by the Wyoming center in December 2003 for oxygen concentrators. At this training, Morrison told trainees that Lincare used a "cookie cutter approach" to marketing, meaning Lincare operated all of its centers across the country in the same way.

In November 2004, Hericks attended a Care Check program training in Livonia, Michigan conducted by Morrison and Mickey McKenzie, National Director of Marketing and Business Development for Lincare Holdings, Inc. At this training, Lincare provided documentation to its new employees regarding Lincare's sales and marketing programs, including the Care Check program. Among the documents were two graphs showing how the Care Check program extended the length of time Medicare patients receive oxygen therapy to seventeen months on average, while the national average was only ten months.

At this training, Lincare employees were taught how to solicit doctors to refer patients to the Care Check program. They were instructed to tell doctors that Lincare, through its provision of services like respiratory therapy and medical office practice management, could save their practices money by reducing the number of patient cancellations. Trainees were told to ask doctors to sign a "Fast Fax" Care Check order form that would enable Lincare employees to visit patients at home and perform clinical assessments on patients who were not yet receiving oxygen therapy. Because Medicare does not cover physician-prescribed home oxygen unless the coverage is justified by an oximetry test measuring blood-oxygen levels, Hericks alleges Lincare would send a therapist free of charge to conduct oximetry tests at thirty-day intervals until the test results indicated the patient would qualify for Medicare covered oxygen therapy. If and when the results suggested the patient could get oxygen therapy, Lincare employees were to inform the doctor to order an oximetry test from an independent testing facility (IDTF) that would officially qualify the patient for Medicare coverage. These therapist visits had a monetary value of at least $85 each. The trainees were also instructed to inform physicians that each Lincare assessment would result, eventually, in a billable patient visit.

The training also included a section on a program called "Naked Care Check." This program involved Lincare convincing a doctor's non-Lincare patients who were using Metered Dose Inhalers (MDIs), which are not covered by Medicare, to switch to liquid Unit Dose (UD) medications, which are covered by Medicare.[4] The switch would increase Lincare's revenue because Lincare does not sell MDIs, but does sell devices to deliver the UD medications.

[4] Under the heading "Naked Care Check," the training materials included a bulleted list stating "Non-Lincare COPD patients, not currently on Unit Dose" and "MDI users." SAC Ex. A, at 6. A prescription by the doctor was required to switch patients to the UD medications.

McKenzie told center managers to give cash incentives to drivers and service representatives for referrals of UD patients.

After this training, Hericks supervised respiratory therapists in making sales calls to doctors and occasionally accompanied the therapists to doctor offices. The visits to doctors' offices sometimes involved buying lunches for a doctor and her staff. For example, in November 2004, Hericks accompanied respiratory therapist Arlene Sudia on a lunch sales call to Dr. Samina Ghazi, which resulted in Dr. Ghazi referring Sudia three patients for Care Checks. Hericks asserts these lunches often cost as much as $250, but does not specify how much money the lunch with Dr. Ghazi cost. In January 2005, Hericks went on another sales call with respiratory therapist Sarah Earl to Dr. Michael Gambel. Hericks's supervisor, Matt Holmes, informed Hericks that Dr. Gambel was to receive preferential treatment because he referred so many patients to Lincare. During this visit, Earl reported to Dr. Gambel about his patients she had visited and which ones needed an IDTF test. Earl also gave him a list of patients that Lincare's Med4home (a division of Lincare Holdings, Inc. that acts as a mail order pharmacy) wanted to refer to him and multiple Fast Fax forms for his signature. Hericks asserts she observed similar visits during her one year tenure at Lincare.

Lincare provides oxygen therapy to approximately 550,000 patients in the United States. According to Lincare's SEC filings, in 2002, 2003, 2004, and 2005, 67% of Lincare's revenues were from Medicare and Medicaid programs, and in 2009, 2010, and 2011, 60% of Lincare's revenues were from such programs. Given the number of claims submitted by Lincare's Casper, Wyoming center and the hundreds of service centers around the country from 2002 to date, it is estimated that Lincare has submitted millions of claims to the Government.

Based on the foregoing allegations, Hericks alleges Lincare violated the False Claims Act in three ways: (1) making kickbacks to federal healthcare beneficiaries, providers, and employees with the intent to obtain referrals to supply durable medical equipment for oxygen therapy to be paid for by federal healthcare payers; (2) causing the submission of false claims to Medicare and other federal health insurance programs based on false statements regarding Lincare's compliance with Centers for Medicare and Medicaid Services' (CMS) regulation forbidding durable medical equipment suppliers from participating in the qualifying oxygen test; and (3) making kickbacks to federal healthcare beneficiaries, providers, and employees with the intent to obtain prescriptions from doctors switching patients from MDIs not covered by Medicare to UD medications covered by Medicare.

DISCUSSION

A. MEDICARE & FALSE CLAIMS ACT

Medicare is a federally-funded health insurance program primarily benefitting the elderly that pays for the costs of certain hospital services and care. *See* 42 U.S.C. §1395 et seq. The Centers for Medicare and Medicaid Services (CMS) is the component of the Department of Health and Human Services (HHS) that administers Medicare. Eligible persons age sixty-five and older may enroll in Medicare Part B to obtain health insurance benefits in return for the payment of monthly premiums in an amount established by CMS. These individuals are known as beneficiaries and the benefits include home oxygen equipment and supplies (durable medical equipment or DME) that are prescribed by a beneficiary's doctor. When a beneficiary receives services from a Part B provider, he may either pay for the service himself and submit the bill to Medicare directly (unassigned claims) or may assign the right to reimbursement to his provider, in which case the provider then submits the bill to Medicare for reimbursement (assigned claim).

Only participant providers may submit assigned claims for payment. In order to become a Part B participant provider, physicians and others, including DME suppliers, must agree to certain conditions including to not make false statements concerning requests for reimbursements and to bill Medicare only for reasonable and necessary services not substantially in excess of the patients' needs. *See, e.g.*, 42 U.S.C. §§ 1320a-7b(a)(1)-(2), 1320a-7a(a), 1395y(a)(1)(A). Lincare is a participating provider in the Medicare Part B program and submits assigned claims directly to federal and state Medicare programs for payment.

The federal healthcare Anti-Kickback Act, 42 U.S.C. § 1320a-7(b)(7), forbids the payments of kickbacks. Specifically, the statute prohibits any person or entity from making or accepting payment in return for referring an individual to a person or entity for the furnishing of any item or service for which payment is made under a federally-funded healthcare program. 42 U.S.C. § 1320a-7b(b)(1), (2). When remuneration is purposefully paid to induce or reward referrals of items or services payable by a federal healthcare program, the Anti-Kickback Act is violated. Compliance with the Anti-Kickback Act is a condition of payment under a federally-funded healthcare insurance program.[5] Claims tainted by kickbacks are "false or fraudulent" claims within the meaning of the FCA. *See id.* § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.").

The primary purpose of the FCA "is to indemnify the Government—through its restitutionary penalty provisions—against losses caused by a defendant's fraud." *United States*

[5] The CMS Provider/Supplier Enrollment Application Forms 855-A and 855-B specifically state "that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions . . . including, but not limited to, the Federal anti-kickback statute . . . ." Presumably, Lincare submitted these forms to the Government to become a Medicare provider.

ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 304 (3d Cir. 2011) (citation omitted). Under the FCA, an individual, known as a relator, can bring civil action on behalf of the Government, and after investigation of the claims, the Government may intervene and proceed with the action. 31 U.S.C. §§ 3730(b)(1), (2). In this case, the Government chose not to intervene. In order to make out a prima facie claim under the FCA a plaintiff must show: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *United States ex rel. Pilecki-Simko v. Chubb Inst.*, 443 F. App'x 754, 759 (3d Cir. 2011) (quoting *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)).[6]

[6] Hericks filed this action in 2007 pursuant to the FCA then in effect and cited causes of action under 31 U.S.C. § 3729(a)(1),(2), and (3). According to the version of the FCA in place in 2007, a person is liable if he "(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid." 31 U.S.C. § 3729(a)(1),(2) & (3) (2006). Under the current version of the FCA, a person is liable if he "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." 31 U.S.C. § 3729(a)(1)(A), (B) & (C).

In response to a Supreme Court decision finding the FCA reached only claims presented to the Government, as distinguished from claims paid with government funds, *see Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662 (2008), Congress amended the FCA with the Fraud Enforcement and Recovery Act (FERA). FERA reworded the FCA to require only presentment of a false claim for payment, not necessarily directly to the Government or with an intent to defraud the Government. *See* 111 P.L. 21, 123 Stat. 1617 (May 20, 2009). These changes were to take effect on the date of enactment (May 20, 2009), and apply to *conduct* on or after that date, except that 3729(a)(1)(B) took effect as if enacted June 7, 2008 and applied to all *claims* under the FCA pending on or after that date. *Id.* at 1625; *see Foglia v. Renal Ventures Mgmt., LLC*, No. 09-1552, 2012 WL 4506014, at *1 (D.N.J. Sept. 26, 2012).

Under either version of the FCA, however, the elements of a prima facie case are the same. *See United States ex rel. Sobek v. Educ. Mgmt., LLC*, No. 10-131, 2013 WL 2404082, at *21 (W.D. Pa. May 31, 2013). Defendants contend to the extent Hericks is pursuing indirect

B. PLEADING STANDARD

Federal Rule of Civil Procedure 8(a)(2) requires "a short and plain statement of the claim showing that the pleader is entitled to relief," which will "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). To withstand a motion to dismiss, the complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The Complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). The court "must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009); *see also Papasan v. Allain*, 478 U.S. 265, 286 (1986) ("Although for the purposes of this motion to dismiss we must take all the factual allegations in the complaint as true, we are not bound to accept as true a legal conclusion couched as a factual allegation."). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Gelman v. State Farm Mut. Auto. Ins. Co.*, 583 F.3d 187, 190 (3d Cir. 2009) (quoting *Iqbal*, 556 U.S. at 678).

Claims pursuant to the FCA are also subject to the requirements of Rule 9(b). *See United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998); *United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 591 (E.D. Pa. 2012).

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claims made prior to FERA, such claims are not cognizable by this Court and must be dismissed. The Court is not persuaded by this argument because although the amendments generally apply to conduct on or after May 2009, the amendment to § 3729(a)(2) (renumbered as § 3729(a)(1)(B)) applies to all claims pending on or after June 7, 2008, and Hericks brought her claim pursuant to this subsection of the statute in 2007. In any event, the Court need not definitively decide whether or not the alleged claims to federal health benefit programs were direct or indirect, or whether or not the amendments apply to Hericks's case, because her claims are dismissed on alternative grounds.

Rule 9(b) requires "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). This heightened pleading standard "requires plaintiffs to plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984); *see also Streck*, 894 F. Supp. 2d at 590-91. Plaintiffs may satisfy this requirement by pleading the "date, place or time" of the fraud, or through "alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Seville*, 742 F.2d at 791. At a minimum, the plaintiff must support her allegation of fraud with essential factual background—the "who, what, when, where, and how of the events at issue." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (citation and internal quotation marks omitted) (discussing the requirements of Rule 9(b) in the context of securities fraud); *cf. United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 440 (3d Cir. 2004) (upholding a summary judgment dismissal because "a False Claims Act plaintiff cannot merely . . . describe a private scheme in detail but then . . . allege simply and without any stated reason for his belief that claims requesting illegal payments must have submitted, were likely submitted or should have been submitted to the Government" (alterations in original) (quoting *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002))).

The Third Circuit, however, cautions against "focusing exclusively on its 'particularity' language [because it is] too narrow an approach and fails to take account of the general simplicity and flexibility contemplated by the rules." *Seville*, 742 F.2d at 791. Instead, the focus

is on whether "each allegation of fraud adequately describes the nature and subject of the alleged misrepresentation." *Id.*; *see also United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04-186, 2006 WL 2642518, at *7 (W.D. Pa. Sept. 13, 2006) ("[F]or the Court to *require* Relators to provide allegations of 'date, place or time' would effectively negate the Third Circuit's instruction that 'Plaintiffs are free to use *alternative means* of injecting precision and some measure of substantiation into their allegations of fraud.'" (quoting *Seville,* 742 F.2d at 791)).

The Court finds even if Hericks's claims could meet the pleading requirements of Rule 8, she fails to meet the Rule 9(b) standard because she has not alleged with particularity the circumstances constituting fraud or mistake nor has she alleged generally Lincare's knowledge regarding the allegedly false claims submitted to the Government.

C. DISMISSAL OF CLAIMS

1. Kickbacks for Referrals to Supply Durable Medical Equipment

In her first claim, Hericks alleges Lincare violated the False Claims Act by making kickbacks to federal healthcare beneficiaries, providers, and employees with the intent to obtain referrals to supply durable medical equipment for oxygen therapy to be paid for by federal healthcare payers. Specifically, Hericks alleges Lincare provided physicians free services such as medical office practice management techniques intended to reduce patient cancellations and enhance physician revenue, smoking cessation therapy, Lincare respiratory therapists for patients referred to Lincare, and expert consulting services to physicians seeking to set up sleep labs. Because Hericks has not stated with particularity the circumstances surrounding these kickbacks, her pleading fails to meet the standards of Rule 9(b), and this cause of action will be dismissed.

First, other than vague references in the opening paragraphs of the SAC, Hericks provides no information about smoking cessation therapy or consulting services for sleep labs, and thus, these allegations of kickbacks fail to meet the particularity standard.

Next, the only description Hericks provides of the alleged "medical office practice management techniques," appears in a single sentence at the beginning of the Complaint and the description of the training Hericks attended in November 2004. In the opening to the SAC, Hericks asserts Lincare reminded patients to make and keep appointments with their doctors and Lincare representatives met patients at the doctors' offices to discuss their health statuses. SAC ¶ 3. She does not explain the meaning of this statement or support her broad allegation with any facts. Nowhere in the Complaint does Hericks describe a situation in which a Lincare employee reviewed a doctor's scheduled appointments to improve office efficiency and profitability or worked as a receptionist directly in a doctor's office. Hericks also does not provide any examples of a time when a Lincare representative accompanied a patient to a doctor visit, and has not alleged that a Lincare representative was ever present during a patient's private doctor appointment. With regard to practice management kickbacks referenced at training, she asserts the trainees were instructed to obtain the doctor's cancellation rates and inform the doctor that through "disease education and management for COPD and CHF patients by Respiratory Therapists in the home" Lincare can help manage the patient base. SAC ¶ 33. Thus, Hericks's assertion that Lincare promised management services seems to actually be a promise to provide a respiratory therapist, a claim which is addressed below. As a result, the allegations regarding practice management techniques are not pleaded with sufficient particularity and will be dismissed.

Hericks asserts Lincare also provided kickbacks in the form of Lincare therapists making personal sales calls to doctors' offices and reviewing the doctor's patient lists for potential oxygen needs. SAC ¶¶ 40, 41. Hericks alleges the sales calls oftentimes involved buying lunch for the doctors, which exceeded the incidental expenditures allowed under the Stark Rules. [7] Hericks recounts one instance when she accompanied a Lincare therapist who brought lunch to Dr. Samina Ghazi's office, but other than stating that sometimes these lunches could cost up to $250, she does not specify how much this particular lunch cost. At the end of this lunch, Hericks alleges Dr. Ghazi gave three patients Care Check referrals, but does not connect these referrals to any claims made to Medicare. She also asserts she accompanied a Lincare respiratory therapist on a visit to Dr. Michael Gambel, during which the therapist reviewed Dr. Gambel's patient list for patients who received free oximetry tests and now qualified for Medicare oxygen and patients who were on Lincare oxygen but not on UD therapy. The therapist also gave Dr. Gambel multiple "Fast Fax" forms to be signed for some of his patients so Lincare representatives could visit those patients at home. However, simply visiting a doctor does not mean kickbacks were given or false claims were made; a therapist making sales calls to doctors does not implicate any fraud. Further, similar to the visit with Dr. Ghazi, Hericks does not allege any claims were submitted to Medicare as a result of these referrals. Hericks has therefore failed to allege fraud with particularity, and this claim will be dismissed pursuant to Rule 9(b).

Hericks's last allegation of kickbacks in her first claim is that Lincare provided respiratory therapy to doctors' patients, but this assertion is also not pleaded with sufficient facts

[7] The Stark law limits certain physician referrals of health services for Medicare and Medicaid patients if the physician has a financial relationship with the entity to which he is referring. However, there are several exceptions including "[c]ompensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per calendar year." 42 C.F.R. § 411.357(k).

to state a plausible claim of fraud. Hericks alleges these therapists offered "free home assessments, including free oximetry tests both before and after patients are prescribed oxygen therapy." SAC ¶ 3. As Defendants pointed out in the oral argument on the motion to dismiss the FAC, Hericks's allegation that Lincare "provided" respiratory therapists is not a claim that as a result of this therapist, the doctor did not have to hire his own therapist, saving him money and resources. Motion to Dismiss Hr'g Tr. 25-26, Feb. 6, 2013 (hereinafter MTD Hr'g). Rather, Hericks alleges these therapists visited patients at their homes to perform clinical assessments before and after they were on oxygen therapy and conducted oximetry tests until the tests indicated the patient would qualify for Medicare covered therapy. SAC ¶ 30. Her claim regarding qualifying oximetry testing is addressed in the next section, but to the extent this allegation refers to visits from Lincare therapists after a patient is already on oxygen, Hericks has not sufficiently pleaded such an arrangement is fraudulent.

Patients on oxygen provided by Lincare are Lincare patients too, and a trained technician visiting a patient at home to check on supplies from the company, and not getting paid, is not an improper kickback, it is proper care. In fact, during oral argument on the motion to dismiss, Hericks's attorney admitted "I don't have a quarrel with the respiratory therapist going [to a patient's house] after the doctor has prescribed oxygen." MTD Hr'g Tr. 40. Rather, the focus of Hericks's claims is on alleged testing done before the patient is a Lincare patient; in other words, Lincare "trying to get patients and new business." *Id*; *see also id.* at 47 ("[W]e're talking about getting new patients, not servicing existing patients.").[8] Furthermore, the prescribing doctor does

[8] According to Defendants, Lincare therapists visit customers' homes to check oxygen saturations at the end of a thirty-day period when the oxygen bottle is near empty, but only for patients who have been properly prescribed home oxygen and use Lincare as their supplier. MTD Hr'g Tr. 12. The respiratory therapist looks at the patient, talks to him, takes vital signs, and tests oxygen saturations. *Id.*

not receive any remuneration as a result of these visits; it is unlikely the doctor would check on the patient at the patient's home or see the patient in his office as often as the Lincare representatives check on their patients.[9] Likewise, the patient is not receiving services the doctors would otherwise provide; the doctor is not the supplier, he simply prescribes the medicine that will then be delivered by the supplier, in this case Lincare.

Hericks also describes a chart she received in training showing the average number of months Lincare's patients received oxygen therapy was seventeen months, which is longer than the national average of ten months, allegedly demonstrating the Care Check program extended the length of time Medicare patients received oxygen therapy. She asserts "[t]he extended time on oxygen did not mean the patients lived any longer, only that they were placed on oxygen sooner [than they would be without the Care Check program.]" SAC ¶ 29. But a patient can only receive oxygen therapy covered by Medicare, as explained in the next section, after qualifying under a test administered by an independent testing facility. Lincare could not influence the qualifying testing, and the fact a Lincare patient receives oxygen therapy sooner than a non-Lincare patient based on a third-party test could actually indicate Lincare patients are receiving better care through the Care Check program than those forced to suffer additional months without oxygen therapy. Further, the extended time on oxygen could be the result of many different benefits in the Care Check program, and does not necessarily mean the patient received free oximetry testing or some illegal remuneration before becoming a Lincare patient.

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[9] As Defendants argued at the motion to dismiss hearing, the patient's doctor might actually lose money because the patient will not have to visit the doctor's office as often if the patient's equipment is being monitored by a third party. MTD Hr'g Tr. 14, 28.

Hericks's pleading that Lincare's allegedly illegal conduct occurred on a national scale also fails to meet the particularity standard of Rule 9(b).[10] Hericks worked for a single training center in Michigan for one year; she has not pleaded actual knowledge of practices occurring in Lincare centers nationwide or for periods of time predating or postdating her employment. In fact, most of her allegations are based on materials she received during her training. To demonstrate Lincare's allegedly fraudulent conduct occurred nationwide, Hericks states a Lincare supervisor told her during training Lincare used a "cookie cutter approach" to marketing. Not only is it unclear what "marketing" means in this context, the supervisor's statement, without more, does not support Hericks's conclusory assertion that illegal kickbacks occurred in every Lincare center. Hericks also fails to plead facts that demonstrate the things she heard in training about other centers, which she claims would be improper in practice, actually resulted in improper claims to Medicare. For example, with regards to the three Medicare claims originating from a Lincare center in Wyoming in 2003, Hericks does not allege these claims resulted from illegal remunerations. She only asserts these claims were submitted when Lincare's illegal practices were in effect, and she does not explain how these submissions related to any specific illegal activity. Lincare is a Medicare provider; it is not illegal for the company to submit legitimate claims to Medicare. Similarly, Hericks's claim that roughly 60% of Lincare's revenue comes from Medicare and Medicaid is not indicative of wrongdoing and does not lead to the conclusion that most of Lincare's revenues derive from fraudulent activity.

The case here is unlike the situation in *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 680 (E.D. Pa. 2010). In that case, although the relator did not identify

[10] Several times in the SAC Hericks asserts Lincare violated the Anti-Kickback Act in its centers throughout the country beginning in 2002. *See, e.g.*, SAC ¶¶ 3, 36, 51. However, as explained above, even if Hericks limited her claims to only those occurring in centers with which she had direct contact, she still fails to meet the Rule 9(b) particularity standard.

at the pleading stage a specific false claim submitted to the Government, the Court denied the defendant's motion to dismiss because the relator described in great detail the defendant's alleged bribes to doctors to prescribe a certain medication and pointed to a sharp increase in total sales of the prescription drug in a short period of time. *Id.* at 679-90. The Court found that "[t]here is no mystery or ambiguity to these allegations" and his "allegations are sufficiently specific both to inform [defendant] of the 'precise misconduct' charged, and to make it unlikely that Relator has commenced this action in bad faith." *Id.* at 680. Here, Hericks has not pointed to a sharp increase in oxygen therapy sales other than reference to a chart she received in training, and she has failed to connect the information on this chart with any illegal acts by Lincare. Further, most of the "kickbacks" she describes are either not pleaded with sufficient detail or do not seem to be kickbacks at all. In sum, Hericks's claims of kickbacks are rooted in conjecture, speculation or supposition; she asks the Court to assume that some claims at some point from some center must have resulted from illegal practices. While it is true Rule 9(b) does not, as a matter of law, require that Hericks allege specific examples of false claims, *see Streck*, 894 F. Supp. at 602 (E.D. Pa. 2012), she must have some "alternative means of injecting precision and some measure of substantiation into [her] allegations of fraud." *Lum v. Bank of Am.*, 361 F.3d 217, 224 (3d Cir. 2004) (quoting *Seville*, 742 F.2d at 791). Hericks, having failed to plead the who, what, and where, has also not provided the required indicia of reliability, and this cause of action will be dismissed.

Even if Hericks pleaded fraud with particularity, Hericks has not pleaded knowledge. To state a claim under the FCA a plaintiff must show the defendant knew the claim was false or

fraudulent,[11] and, as Rule 9(b) states "malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Hericks's pleading fails to meet even this low standard because she has not made sufficient factual allegations that would reasonably permit the inference Lincare knowingly presented or caused to be presented a false claim. Hericks asserts Lincare knew it was illegal to provide these free services to doctors and beneficiaries in order to gain business by pointing to various pronouncements and administrative policies. For example, in 1995, the Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS), issued a special fraud alert identifying practices that violate the Anti-Kickback Act, including offering inducements to providers and beneficiaries to gain federal healthcare referrals. While this alert discusses the danger of a medical supplier violating the Anti-Kickback Act, it focuses on nursing facilities. OIG Special Fraud Alert, 60 F.R. 40847 (June & August 1995). The Alert also mentions kickbacks in exchange for referrals, but discusses referrals of reimbursable home health services providers, and not suppliers like Lincare. Therefore, although this Alert addresses conduct that is potentially improper under the Anti-Kickback Act, it does not contain warnings pertinent to Lincare. Lincare's awareness that kickbacks are illegal does not demonstrate Lincare's knowledge that the kickbacks asserted in this Complaint were illegal.

Hericks also asserts through Lincare's application to be a provider in the Medicare Part B program, Lincare certified to CMS that it would abide by the Medicare laws, demonstrating knowledge that claims tainted by the payment of kickbacks are false or fraudulent. In addition, Hericks asserts that in 2006, Lincare paid a $10 million fine to the federal Government to settle

[11] The FCA defines "knowing" and "knowingly" to "mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(1)(A).

allegations it had engaged in a pattern of paying kickbacks to physicians, and Lincare entered into a corporate integrity agreement with the Government wherein it acknowledged that it was aware that offering free services or products to patients or healthcare providers was a violation of the FCA and promised not to engage in this conduct. However, again, Lincare's awareness of the law does not demonstrate Lincare's knowledge that claims it submitted to Medicare were tainted with illegal kickbacks. Hericks has not sufficiently pleaded Lincare's knowledge as to any false claims submitted to Medicare, and her first cause of action fails on this ground as well.

2. Provision of Qualifying Oxygen Tests

In her second claim, Hericks asserts Lincare violated the False Claims Act by causing the submission of false claims to Medicare and other federal health insurance programs based on false statements regarding Lincare's compliance with CMS's regulation forbidding durable medical equipment suppliers from participating in qualifying oxygen tests.

CMS's Local Coverage Determination for Oxygen and Oxygen Equipment (LCD) sets forth the process a prescribing physician must follow to obtain a qualifying oxygen blood gas study in order to then prescribe home oxygen therapy eligible for reimbursement by Medicare.[12] According to the LCD, the qualifying blood study must be performed either by a physician or by a qualified provider or supplier of laboratory services. LCD at 2. However, a supplier, like Lincare, is "not considered a qualified provider or a qualified laboratory for purposes of this policy. Blood gas studies performed by a supplier are not acceptable. In addition, the qualifying blood gas study may not be paid for by any supplier." *Id.* at 4. Beneficiaries are permitted to self-administer home based overnight oximetry tests, but only under the direction of an independent diagnostic testing facility (IDTF). *Id.* at 5. A DME supplier may deliver the testing unit to the

[12] By leave of this Court, the parties submitted letter briefs on the issue of the LCD. The LCD is available at http://www.cms.gov/medicare-coveragedatabase/details/lcddetails.

beneficiary's home, but the "DME supplier may not create . . . written instruction, provide verbal instructions, answer questions from the beneficiary, apply or demonstrate the application of the testing equipment to the beneficiary, or otherwise participate in the conduct of the test." *Id.* Instead, the IDTF must provide written instructions and be accessible to the beneficiary in the event the beneficiary has questions or concerns. *Id.* The test results are sealed and sent to the IDTF; "[i]n no case may the DME supplier access or manipulate the test results in any form." *Id.* Thus, Lincare is not permitted to be involved in the testing that will lead to prescription of oxygen therapy.

Hericks asserts that normally the test that would qualify a patient for oxygen therapy paid for by Medicare would take place in a doctor's office, but through the Care Check program, Lincare performed oximetry tests and provided the results to the doctor. SAC ¶ 31. In the same paragraph of the SAC, however, Hericks continues "[i]f the patient's results suggested they could get oxygen therapy that would be paid for by Medicare, Lincare's employees are trained to tell the doctor to order an oximetry test from an Independent Testing Facility ("IDTF") to provide the test that would qualify for and trigger Medicare coverage." *Id.* Hericks has not pleaded any facts that Lincare subverted the system mandated by CMS, and in fact acknowledges that Lincare prompted doctors to arrange for an IDTF to conduct an appropriate qualifying test. The LCD concerns oxygen testing done on patients in order to determine whether the patient qualifies to receive oxygen, and Hericks admits testing had to be done by an appropriate third party for any supplies to then be ordered for oxygen therapy. Whether or not some other rule or regulations prohibit Lincare from performing tests to encourage doctors to then order qualifying tests regulated by the LCD, the LCD does not address the type of pretesting

Hericks alleges Lincare performed, and she has thus not pleaded Lincare violated CMS's LCD regulations.

Although not stated in the Complaint, Hericks suggested in oral argument that through the provision of these pretests, Lincare improperly influenced a patient's choice of supplier. Even if this alleged conduct was the basis for her claim, her pleading still fails to satisfy Rule 9(b).

First, it is not clear pretesting would actually violate the Anti-Kickback Act. Hericks asserts Lincare's pretesting is strictly prohibited by the OIG as evidenced by two Advisory Opinions issued in 2006. The first found that an arrangement in which a DME supplier provides patients with free overnight oximetry tests *could* violate the Anti-Kickback Act, even if such a test could not qualify a beneficiary for oxygen coverage by the Medicare program. OIG Advisory Opinion No. 06-20, at 2, Nov. 1, 2006. Specifically, "notwithstanding that the tests . . . would have no value for the purpose of qualifying for Medicare coverage," such testing "would lead a reasonable beneficiary to believe that he or she is receiving a valuable service that may expedite access to covered oxygen supplies and contribute to a successful clinical outcome." *Id.* at 5. The testing would "initiate a relationship with the beneficiary, and it is reasonable and probable that for future purchases the beneficiary would select a supplier with whom he or she is already familiar." *Id.* at 5-6. Further, the OIG found that given the testing is offered free of charge, delivered to the home, and recommended by the beneficiary's doctor, it seems likely the supplier knows or should have known the provision of the service would influence the beneficiary's selection of that supplier for Medicare-payable supplies. *Id.* at 6. In the second Advisory Opinion, the OIG concluded a home health agency's provision of free preoperative home safety assessments to potential customers *could* violate the Anti-Kickback Act. OIG Advisory Op. No. 06-01, at 6, Mar. 20, 2006. Hericks asserts these opinions demonstrate not

only that the testing done by Lincare violates the Anti-Kickback Act, but also that Lincare knew its actions were illegal.

The OIG's opinions, however, are advisory, and "has no application to, and cannot be relied upon by, any other individual or entity [other than the requestors]." OIG Advisory Op. No. 06-20, at 7. Further, the opinions state only that such testing *could* be grounds of the imposition of civil penalties under the Act. These opinions do not establish that Lincare's oximetry testing violated the Anti-Kickback Act.

Even if providing these tests was in violation of the Anti-Kickback Act, Hericks's pleading does not meet the standards of Rule 9(b) because she has not provided essential factual background regarding this claim. She does not allege any facts regarding specific patients, doctors, or offices. She gives no examples of a Lincare representative performing an oximetry test on a non-Lincare patient. Although she specifically alleges one doctor referred three patients to the Care Check program after a visit with a Lincare representative, she does not state these patients were given oximetry tests or even visited by Lincare representatives. Hericks offers training materials to support her claim, but the materials do not definitely instruct such testing and are not sufficient to demonstrate pretesting actually occurred.[13] Rather the materials describe the steps involved when performing a "clinical assessment," which could occur with a patient

[13] When considering a 12(b)(6) motion to dismiss for failure to state a claim upon which relief can be granted, the Court must accept as true all well-pleaded allegations in the complaint and view them in the light most favorable to the nonmoving party. *See Angelastro v. Prudential-Bache Sec., Inc.*, 764 F.2d 939, 944 (3d Cir. 1985). The Court may also consider exhibits attached to the complaint, matters of public record, and records of which the Court may take judicial notice. *See Stanton v. City of Philadelphia*, No. 10-2726, 2011 WL 710481 (E.D. Pa. Mar. 1, 2011) (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322, (2007); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). Hericks has attached to the SAC several pages of training material she received from Lincare, and the Court finds it appropriate to consider their contents in evaluating the instant motion to dismiss.

already receiving oxygen therapy. MTD Ex. A, at 2. In a flow chart titled "Patient Enrollment and Completion Process," the third step is "Lincare completes assessment and with patient schedules apt with Dr" and the fourth step is "Lincare Sales Rep delivers assessment next day" and "obtains rx of O2 or UD if patient need and rx for repeat pulse ox to show improvement." *Id.* at 3. Thus, the only time the training materials mention a "pulse ox" test is after an instruction to obtain a prescription from a doctor for oxygen, and the doctor could only write this prescription after testing done by an IDTF. This flow chart does not indicate that Lincare performed any testing before the IDTF test or that the initial assessment involves an oximetry test. Because Hericks's claims are conclusory allegations of fraud based on speculation and conjecture and do not have any measure of substantiation, she has failed to meet the particularity requirements of Rule 9(b) and this cause of action will be dismissed.

Additionally, similar to the first cause of action, even if Hericks pleaded fraud with particularity, Hericks has not adequately pleaded knowledge. The advisory opinions upon which she relies to demonstrate Lincare knew pretesting was illegal were issued in 2006, and Hericks does not establish knowledge as to any acts occurring after termination of her employment in May 2005. Thus, Lincare was not put on notice by these opinions that such pretesting could violate the Act, and Hericks's claims fails to meet the Rule 9(b) standard regarding knowledge.

3. **Third COA: Kickbacks to Employees**

In her third and final claim, Hericks alleges Lincare violated the FCA by making kickbacks to obtain prescriptions from doctors switching patients from MDIs not covered by Medicare to UD medications covered by Medicare. Even though in the cause of action Hericks alleges these kickbacks for referrals of UD patients were given to "beneficiaries, providers, and employees," SAC ¶ 59, the bulk of her pleadings only allege the cash incentives were given to

"drivers and service representatives," in other words, Lincare employees, SAC ¶ 36.[14] Further, although she alleges Lincare made cash payments to employees for both general referrals of patients and referrals of patients who would switch from MDIs to UD medications, her pleading focuses on the latter. Hericks includes photos of posters at Lincare's center in Brook Park, Ohio, adverting cash bonuses to employees who obtain UD referrals ($15 for each referral). SAC, at 14. She also claims Lincare trainees "were told when they came across [patients using MDIs] to get them to switch to liquid United Dose ('UD') medications, that are covered by Medicare." *Id.* ¶ 35. She submits training materials, including a slide listing under the title "Naked Care Check" the phrases "Non-Lincare COPD patients," "Not currently on United Dose," and "MDI users." *Id.* Ex. A, at 6.

The statute of limitations for FCA claims is six years. 31 U.S.C. § 3731(b)(1) ("A civil action under section 3730 may not be brought . . . more than 6 years after the date on which the violation of section 3729 is committed."). Hericks's raises her specific claims about the UD medication referrals for the first time in her SAC, which she filed March 28, 2013. However, Hericks worked for Lincare for one year beginning in May 2004 and has not asserted any knowledge as to payments of kickbacks occurring after her termination. Thus, the very latest her claim regarding UD medication could have accrued is May 2005, and, to come within the six-year statute of limitations period, she had to file her Complaint by May 2011.

[14] The Court reviews the third claim as applicable to the alleged kickbacks given to Lincare employees. While Hericks generally asserts that Lincare obtained the prescriptions necessary to switch patients from MDIs to UD medications by "providing doctors with free office and respiratory therapy services of Lincare employees," SAC ¶ 35, she does not expand upon this allegation; her further discussion of kickbacks for UD medications only involves cash payments to Lincare employees. If the Court generously construes her allegation involving UD medication as an assertion doctors were more inclined to write prescriptions for UD medications because they received "free office and respiratory services," then the Court will dismiss this claim for the same reasons it dismisses her other allegations of kickbacks to doctors for patients referrals found Count One—failure to plead facts necessary to meet the particularity standards of Rule 9(b).

The statute of limitations, however, will not bar Hericks's claims if the UD allegations "relate back" to the claims contained in the FAC, because in that case, the SAC would be treated as if it had been filed at the time of the original Complaint.[15] *See Glover v. F.D.I.C.*, 698 F.3d 139, 145 (3d Cir. 2012). Under Federal Rule of Procedure 15 "[a]n amendment to a pleading relates back to the date of the original pleading when . . . the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." Fed. R. Civ. P. 15(c)(1)(B). For an amended complaint to relate back to an original pleading, there must be "a common core of operative facts in the two pleadings," and the amendments must "restate the original claim with greater particularity or amplify the factual circumstances surrounding the pertinent conduct, transaction or occurrence in the preceding pleading." *Bensel v. Allied Pilots Ass'n*, 387 F.3d 298, 310 (3d Cir. 2004). Further, the opposing party must have "had fair notice of the general fact situation and legal theory upon which the amending party proceeds." *Id.* Indeed the "touchstone for relation back is fair notice, because Rule 15(c) is premised on the theory that 'a party who has been notified of litigation concerning a particular occurrence has been given all the notice that statutes of limitations were intended to provide.'" *Glover*, 698 F.3d at 146 (quoting *Baldwin Cnty. Welcome Ctr. v. Brown*, 466 U.S. 147, 149 n.3 (1984)).

[15] Hericks filed her original Complaint on behalf of the United States on January 20, 2007, and it remained under seal until the United States notified the Court of its intention not to intervene in the action on July 2, 2012. By Order of July 6, 2012, the Court directed the Complaint be unsealed and served upon the Defendants. Under Civil Rule of Procedure 15, a party may amend its pleading once as a matter of course within twenty-one days after serving it. Fed. R. Civ. P. 15(a)(1)(A). In this case, Lincare waived service on October 24, 2012, and Hericks filed the FAC November 2, 2012. Lincare did not challenge the relation of the FAC to the original Complaint, and, under Rue 15, when an amendment relates back, the "amendment to a pleading relates back to the date of the original pleading." Thus, the FAC relates back to the date of the original Complaint, and the relation-back arguments presently before the Court concerns the relation only between the SAC and the FAC.

Hericks's allegations in the SAC regarding UD medication do not relate back to the claims she asserted in the FAC, and therefore her third claim is barred by the applicable statute of limitations. Hericks's FAC addressed Lincare's Care Check program and specifically focused on Lincare's provision of free oximetry testing to beneficiaries and inducements to doctors in return for patient names who were in need of oxygen. FAC ¶¶ 19, 21-27, 30. She asserted Lincare "routinely offered, without charge, oximetry testing, respiratory therapy, smoking cessation consultations, and transportation to doctor's offices to beneficiaries for the purpose of inducing these patients to choose Lincare as their DME supplier." FAC ¶ 27. She also alleged Lincare offered physicians increased business by reminding patients of appointments, encouraging patients to schedule new appointments, and driving patients to appointments. FAC ¶ 29. Nowhere in the FAC does Hericks mention UD or MDI medications or payments made to Lincare employees.

Hericks asserts her references in the FAC to "services," "other DME items," and "other actions," encompasses her assertion Lincare offered kickbacks for UD referrals. *See, e.g.*, FAC ¶¶ 10, 11, 27. She also argues UD medications are an integral part of the Care Check program, and therefore any reference to the Care Check Program includes claims for both oxygen and UD medications.[16]

[16] As an alternative argument, Hericks asserts the statute of limitations has been tolled for all claims brought under the FCA since 2002 pursuant to the Wartime Suspension of Limitations Act (WSLA), 18 U.S.C. § 3287. Under the WSLA, "[w]hen the United States is at war or Congress has enacted a specific authorization for the use of the Armed Forces" then the running of any statute of limitations applicable to any offense "involving fraud or attempted fraud against the United States or any agency thereof in any manner . . . shall be suspended until 5 years after the termination of hostilities." 18 U.S.C. § 3287. Hericks asserts the war in Iraq began in 2002, and thus the statute of limitations for her FCA claims has been tolled, and the new allegations in her SAC are timely. The Eastern District, however, has held that the tolling provisions of the WSLA do not apply in nonintervened FCA cases. *See United States ex rel. Bergman v. Abbot Labs.*, No. 09-4264, 2014 WL 348583, at *16 (E.D. Pa. Jan. 30, 2014); *see also United States ex*

The business of selling devices for UD medications is not the business of providing home oxygen. Based on the FAC, Lincare would only have been aware Hericks was challenging the manner through which Lincare came to provide home oxygen therapy and would not have known she was also challenging the referral of UD patients. Further, Hericks's claims that remunerations were given to doctors in exchange for patient referrals does not alert Lincare to allegations remunerations were given to Lincare's own employees. Hericks's new claims do not "expound[] upon and further details the factual scenario and breach claims that were roughly sketched in [her] original Complaint." *Bensel*, 387 F.3d at 310. UD medications are different than oxygen therapy, and presumably do not require the same qualified testing as home oxygen. *See supra* pp. 19-21. In fact, even the training materials seem to separate UD medication from the Care Check Program. For example, under a slide titled "Assist the Sales Rep (External)," trainees are directed to "[s]chedule sales calls to discuss Unit Dose *and* Care Check." SAC, Ex. A, at 4 (emphasis added). Because the UD allegations in the SAC do not relate back to the FAC and because Hericks had to file any complaint regarding UD medications by May 2011, her third claim is barred by the statute of limitations and will be dismissed.[17]

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rel. Emanuele v. Medicor Assocs., Slip Copy, No. 10-245, 2013 WL 3893323, at *7 (W.D. Pa. July 26, 2013). In *United States ex. rel. Bergman v. Abbot Laboratories*, the district court found, based on the legislative history of the WSLA and other Eastern District decisions declining to extend the FCA's tolling provision to nonintervened cases, the "WSLA does not toll the FCA's statute of limitations for relators without the Government's intervention, especially when those cases do not involve military or war-related contracts." 2014 WL 348583, at *16. This Court agrees, and finds the WSLA does not toll the statute of limitations in this case.

[17] Even if this claim is not barred by the statute of limitations, the cash payments to Lincare employees may fall under a safe harbor provision of the Anti-Kickback Act. The OIG has enacted safe harbors designating certain practices as immune from the Anti-Kickback Act. Under the bona fide employee safe harbor, 42 C.F.R. § 1001.952(i), payments to employees "for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs" is not considered remuneration and therefore, cannot form the basis of the Anti-Kickback Act violation. 42 C.F.R.

§ 1001.952(i). Further, the Anti-Kickback Act itself provides that "illegal remunerations" does not include "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services." 42 U.S.C. § 1320a-7b(b)(3)(B).

Hericks asserts this safe harbor provision does not apply to the cash payments in this case because the payments were not "for employment in the provision of covered items or services," but instead were for referrals of patients eligible to receive Medicare-covered medications. To support her claim she relies upon a letter written in 1992 from the Associate General Counsel of the Health and Human Services OIG to an assistant in the Office of the Associate Chief Counsel of the IRS which explains, in a footnote, that referrals do not represent covered items or services so "payments to employees which are for the purpose of compensating such employees for the referral of patients would likely not be covered by the employee exemption." Letter from D. McCarty Thornton, Associate General Counsel, HHS OIG, to T.R. Sullivan, IRS, Dec. 22, 1992 at n.2, *available at* https://www.oig.hhs.gov/fraud/docs/safe harborregulations/acquisition122292.htm (last visited March 24, 2014).

Hericks also relies on two cases, not from this district. In *United States v. Starks*, the Eleventh Circuit found that payments made by a director of a drug addiction treatment center at a Medicaid-provider hospital to two state employees working in a nonprofit center for drug abuse in exchange for referrals of patients to his center violated the Anti-Kickback Act. 157 F.3d 833, 839 (11th Cir. 1998). In *United States ex rel. Obert-Hong v. Advocate Health Care*, the district court granted defendants' motion to dismiss and found the Anti-Kickback Act does not prohibit hospitals from requiring employed doctors to make referrals, provided that the compensation arrangements are not contingent on the volume or value of referrals. 211 F. Supp. 2d 1045, 1050 (N.D. Ill. 2002). The court went to state, even if the hospital provided doctors with various perquisites, because the doctors were employees, those perquisites were subject to the bona fide employee exception. *Id.* at 1049.

These sources do not establish that the cash payments to employees in this case are illegal kickbacks. The letter from the Associate General Counsel concerns the acquisition of physician practices by hospitals and the possible payments to those physicians; not only is this letter inapposite to this case, which involves bona fide employees receiving payment from their employer while working for that employer, it is over twenty years old and the author also only suggested in a footnote that payment for referrals of patients would "likely" not be covered by the employee exemption. Similarly, *Advocate Health Care* concerns the acquisition of medical practices by a hospital, and in fact indicates such payments to employees would be covered by the employee exception. Finally, in *Starks*, the individuals received payment from the treatment center only for referrals and not for any legitimate service eligible for Medicare reimbursement. In this case, the employees are employed by Lincare for more than simply referrals. Furthermore, as Defendants point out, under Hericks's reasoning, all payments to sales representatives who sell healthcare goods and services would be improper because those payments would result from referrals.

Because the safe harbor language applies to payment to individuals for employment in the provision of covered items and services, and because the Lincare employees are employed in the provision of covered items and services, the cash bonuses for referrals are not necessarily illegal remuneration in violation of the Anti-Kickback Act, providing an additional reason for the Court to dismiss this claim.

An appropriate order follows.

BY THE COURT:

/s/ Juan R. Sánchez
Juan R. Sánchez, J.